NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ORTHO-MCNEIL PHARMACEUTICAL, INC., Plaintiff, v. MYLAN LABORATORIES INC., et al., Defendants.	Civil Action Nos. 04-1689, 06-757 and 06-5166 Consolidated Cases **OPINION**

CHESLER, District Judge

This matter comes before this Court on the motion by Plaintiff Ortho-McNeil Pharmaceutical, Inc. ("Ortho") for entry of final judgment against Defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan"). This case concerns infringement of U.S. Patent No. 4,513,006 (the "'006 patent"). With this motion, Ortho seeks three main elements of relief: 1) entry of a permanent injunction; 2) change of the effective date for approval of Mylan's ANDAs; and 3) an award of taxable costs.

The Supreme Court has reaffirmed the longstanding test for entry of a permanent injunction:

> According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between

> the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1839 (2006). As to the first factor, this Court has determined that Ortho's patent is valid and that Mylan has infringed it; Ortho has suffered an irreparable injury. As to the second factor, the remedies available at law, such as money damages, are inadequate to compensate for the irreparable injury. In ruling on Ortho's motion for a preliminary injunction, this Court decided that the third and fourth factors, the balance of hardships and the public interest, weighed in favor of granting Plaintiff's application for injunctive relief. (Opinion of October 23, 2006 at 17-18.) Having considered these four factors, this Court finds that Ortho has shown that it is entitled to the grant of a permanent injunction. Indeed, Defendant concedes that, based upon the Court's prior findings, Plaintiff is entitled to a permanent injunction.

The parties dispute whether the Hatch-Waxman Act (the "Act") authorizes this Court to reset the effective date of Mylan's ANDAs. The relevant provision states:

> (4) For an act of infringement described in paragraph (2)--
> (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed . . .

35 U.S.C. § 271(e). Ortho contends that this provision requires this Court to reset the effective date of Mylan's ANDA. In opposition, Mylan argues on a number of grounds that the Act does not authorize this Court to change the effective date if the FDA has already set it.

Mylan's first argument is textual: the phrases "effective date" and "to be a date" should be read to imply a condition for the grant of authority to the Court. This implied condition limits the Court's authority to situations in which an effective date has not already been set. Because

the FDA has already approved the ANDA, and thus the effective date has been set, Mylan argues, this Court may not reset the date pursuant to § 271(e)(4)(A).

This argument is unpersuasive on several grounds. First, as a matter of textual analysis, Mylan rests its argument on the assertion that "to be a date" is a phrase using the future tense. It is not. As an elementary matter of grammar, "to be" is an infinitive. This removes the textual foundation for Mylan's argument. Second, as to Mylan's contention that a Court cannot set an effective date of an approval when the effective date has already been set, this is meritless.

Third, Mylan looks for support in the language of 21 U.S.C. § 355(j)(5), which sets the rules for the FDA's handling of ANDAs. Mylan asserts that § 355(j) limits § 271(e)(4)(A) relief. The statutory language does not support Mylan's position. While this section does make reference to § 271(e)(4)(A), it does so to make rules for the FDA, not for the district court. Section 355(j)(5) does not concern the authority of the district court; it limits neither the availability of remedies under § 271(e)(4)(A), nor the authority of the district court.

Moreover, as Ortho observes, the legislative history of the Act supports its interpretation. See H. R. REP. NO. 98-857, pt. 1 (1984) ("If the infringing party has not begun commercial marketing of the drug, injunctive relief may be granted to prevent any commercial activity with the drug and the FDA would be mandated to make the effective date of any approved ANDA not earlier than the expiration date of the infringed patent. . . In the case where an ANDA had been approved, the order would mandate a change in the effective date.") As Ortho contends, the plain language here shows that Congress envisioned the factual scenario in which the ANDA had been approved, and intended that the district court then change the effective date.

Finally, Ortho points to the decision of the D.C. Circuit in Mylan Labs., Inc. v.

Thompson, 389 F.3d 1272 (D.C. Cir. 2004), a case which, though addressed to the actions of the FDA rather than the district court, reflects that appellate Court's understanding that, when the FDA has granted approval prior to a district court's award of 35 U.S.C. § 271(e)(4)(A) relief, a delay in the effective date should result. Id. at 1282 n.8.

For all these reasons, this Court rejects Mylan's argument, and will delay the effective date of the ANDAs pursuant to 35 U.S.C. § 271(e)(4)(A).

For the reasons stated above, Ortho's motion for entry of final judgment is **GRANTED**.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: March 20, 2007